DEN-MAT HOLDINGS, LLC
2727 SKYWAY DRIVE
SANTA MARIA, CA 93455

K110079
FEB 10 2011

510(k) Summary of Safety and Effectiveness

Den-Mat Holding's Sapphire Plus STM 3W Diode Laser

Submitted for:	Den-Mat Holdings, LLC 2727 Skyway Drive Santa Maria, CA 93455
Phone:	805-922-8491
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Contact Person:	Alan B. Matthews, ext. 2927
Date Prepared:	7 December 2010
Device Proprietary Name(s):	Sapphire Plus STM 3W Diode Laser
Common or Usual Name:	808 nm Diode Laser (Class 4 laser)
Product Classification:	Laser instrument, surgical
Product Code:	GEX
Predicate Device(s):	Ivoclar Vivadent, Inc. Odyssey Navigator Diode Laser (K062258); Zap Lasers, LLC Styla MicroLaser/StylaOrtho Laser (K081214); Ivoclar Vivadent, Inc. Odyssey 2.4G (K050453)

Rationale for Substantial Equivalence

Both the subject and predicate laser devices share similar intended uses and indications for use, technical characteristics, features, and specifications. The laser characteristics of the Sapphire Plus STM Laser, including working and aiming beam wavelengths and outputs, laser delivery methods, safety features, and performance specifications are similar to those of the cleared *Odyssey Navigator, Odyssey 2.4G,* and *Styla MicroLaser* Diode Lasers. The laser operating system and controls of the subject device are similar to those used by the previously-cleared predicate devices that have proven safety and effectiveness records in the treatment of the claimed indications. Safety and performance test results have been shown to satisfy applicable international standards recognized by the Agency.

Intended Uses and Indications for Use

The Sapphire Plus STM Laser is intended for use in dental intraoral soft tissue general, oral maxilla-facial and cosmetic surgery. It is intended for ablating, incising, excising, vaporizing and coagulation of soft tissues using a fiber optic delivery system. Indications include excision and incision biopsies; hemostatic assistance; treatment of apthous ulcers; frenectomy; frenotomy; gingival incision and excision; gingivectomy; gingivoplasty; incising and draining abscesses; operculectomy; oral papillectomy; removal of fibromas;

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soft tissue crown lengthening; sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket); tissue retraction for impression; and vestibuloplasty.

Device Description

The Sapphire Plus STM Laser is a plug-in option for the Sapphire Plus Light Source Unit. The Sapphire Plus Light Source Unit contains a xenon arc lamp that, depending on which handpiece is attached, has been cleared for use as either a Curing/Whitening attachment (K081287) or as an adjunct for visual oral tissue examination (K073483). In both cases, these two attachments use different portions of the broad-spectrum xenon arc light's emissions to perform their clinical functions.

Like the other two attachments for the Sapphire Plus Light, the Sapphire Plus STM Laser also plugs into the Sapphire Plus Light. Unlike the other two attachments, however, when the Sapphire Plus STM Diode Laser is attached to the Sapphire Plus Light, only low-voltage DC current –not visible light -- is sent to the Laser. The Sapphire Plus STM Diode Laser is comprised of two basic parts: the control box ("control module") with microprocessor and user interface, and the Laser Handpiece containing the working and aiming beam laser diodes and the laser ON/OFF switch. The Control Module interface allows selection of mode (continuous wave or pulsed) and laser output, provides visual indications of power settings and of the unit's status, and features the unit's footswitch jack and operating key switch and the Emergency STOP button. The Laser Handpiece is found at the end of a six foot long power/communications cord that is plugged into the Control Module's light guide port. The Handpiece houses the 808 ± 5nm laser working beam diode and the 640 ± 10nm aiming beam diode and control board, optics and heat sink, on/off switch, and the disposable fiberoptic tip assembly. An optional footswitch is available that plugs into the control module and can be used to activate the laser working beam instead of the handpiece on/off actuator. The Sapphire Plus STM Laser is powered by a 15W, 5 VDC rechargeable lithium-ion battery that receives its energy from the Sapphire Plus Light Source Unit.

Conformity to International Standards

The Sapphire Plus STM Laser complies with the performance requirements listed in 21 CFR 1040.10 and 1040.11, with permissible deviations pursuant to Laser Notice 50, dated July 26, 2001. Additionally, the subject device has been shown to conform to the same international electrical safety standards for electrical medical devices in general, and lasers in particular, as the predicate devices, including electrical safety and electromagnetic compatibility and resistance to interference (EMC and EMI): IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, IEC 60825-1, and IEC 60601-2-22.

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NON-CLINICAL COMPARISONS

Comparative Performance Data

The Sapphire Plus STM Diode Laser has been tested side-by-side against one of the predicate devices. Measurements of the output of the subject device's working beam ranging from 0.1 to 3.0W output in Continuous Wave and Pulse modes were shown to vary from the unit's settings by an average of only 1.4% in CW and 0.5% in P compared to the predicate's variance of 2.2% in CW and 2.7% in P. The intended performance of these devices, based on IEC 60601-2-22, is that laser output should vary from the device's setting by less than ± 20% of the setting. Both the subject and predicate devices have been shown to satisfy this standard, with the subject device demonstrating less variability (more control) than the cleared predicate device.

The Table "Comparison of Lasing Characteristics" immediately following and Table 1 Key Features and Characteristics provide tabular comparisons of the subject device technical and operational characteristics to those of the predicate devices.

Comparison of Lasing Characteristics

Device Description:	Sapphire Plus STM	Odyssey Navigator	Styla MicroLaser	Odyssey 2.4G
Output range, CW	0.1 – 3.0W	0.1 – 3.0W	2W maximum	0.1 – 5.0 W
Increments available	0.1W	0.1W	unknown	0.1W
Energy available (per 1 second emission, CW)	3J	3J	2J	5J
Output range, P	0.1 – 3.0W	0.1 – 3.0 W	0.1 – 2.0 W	0.1 – 5.0W
Increments available	0.1W	0.1W	0.1W	0.1W
Method for pulsing	Digital emission control	Digital emission control	Digital emission control	Digital emission control
Frequency of pulse	4 Hz	10 Hz	10 Hz	1 Hz
Pulse train duration	0.125 seconds	0.05 seconds	0.05 seconds	0.5 seconds

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Duty cycle	50%	50%	50%	50%
Energy available (per 1 second emission, CW @ maximum output)	3.0J	3.0J	2.0J	5.0J
Fiberoptic tip diameter	400 µm	400 µm	400 µm	400 µm
Beam diameter	150 µm	unknown	unknown	unknown
Working Beam Wavelength (nm)	808 nm (±5nm)	810 (±20 nm)	808 (±5 nm)	810 nm (±20 nm)
Light source	Single emitter solid state diode	Single emitter solid state diode	Single emitter solid state diode	Single-emitter solid state diode
Beam divergence angle	9° (± 1°)	9° (±1°)	unknown	9° (±1°)
Aiming beam present?	Yes	Yes	Yes	Yes
If present, wavelength	640 nm (±10nm)	630 – 650 nm	650 nm	630 – 660nm (± 15nm)
Output	2mW	2 mW	5 mW	2mW
Adjustable?	Yes, from 0 mW (OFF) to 2 mW	Yes, from 0 mW (OFF) to 2mW	Yes	Yes, from 0 mW (OFF) to 2 mW
Laser medium	GaAlAs Laser Diode	GaAlAs Laser Diode	GaAlAs Laser Diode	GaAlAs Laser Diode
Cooling method	Convection	Convection	Convection	Air cooled fan
Aperture stop present?	Yes	Unknown	Unknown	Unknown

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Comparison of Features and Characteristics

Table 1, following, lists key Features and Characteristics of the subject and three predicate devices.

Table 1.

	Den-Mat Holdings, LLC Sapphire Plus STM laser	Ivoclar Vivadent, Inc. Odyssey Navigator Diode Laser	Zap Lasers, Inc. Styla MicroLaser Diode Laser	Ivoclar Vivadent, Inc Odyssey 2.4G Diode Laser
Wavelength	808 ±5 nm	810 ±20 nm	808 ±5 nm	810 ±20 nm
Power	0.1 – 3.0 W (CW) & (Pulse)	0.1 – 3.0 W (CW & Pulse)	2.0 W maximum	0.1 – 5.0 W (CW & Pulse)
Aiming Beam	640 nm (±10 nm), maximum 2 mW (adjustable)	630 – 650 nm, maximum 2 mW (adjustable)	650 nm, maximum 5 mW (adjustable)	630 - 650 nm, maximum 2 mW (adjustable)
Cooling System	Convection cooled	Fan air cooled	Convection cooled	Fan air cooled
Pulse Control	Digital emission control	Digital emission control	Digital emission control	Digital emission control
Laser Source	Solid-state diode	Solid-state diode	Solid-state diode	Solid-state diode
Power Requirements	15W 5VDC supplied from 110 - 120 VAC @ 60 Hz or 220 - 240 VAC @ 50 Hz (switchable)	100-240 VAC @ 50-60 Hz, 0.5A (switchable)	100-240VAC @ 50-60 Hz, 0.8A max (switchable)	100-240 VAC @ 50-60 Hz, 1.5A (switchable)
User Interface	Membrane touch pad, LCD Display, LED Indicators	LCD Touch Screen	Membrane touch pads, LED Display	Membrane touch pads, LCD display
Fiberoptic Tip	Disposable, 400 µm unit dose	Disposable, 400 µm unit dose	Disposable, 400 µm unit dose	6 meter fiber cartridge, 400 µm diameter
510(k) Number	Pending this application	K062258	K081214	K050453

Studies from the Literature Showing Safety and Effectiveness of 808 nm Diode Lasers Used in Dental Intraoral Soft Tissue General, Oral Maxilla-facial and Cosmetic Surgery

The literature abounds with studies that describe the safe and effective uses for 810 nm diode lasers for soft tissue indications. This application includes references to articles that describe the use and effectiveness of soft tissue diode lasers in intra-oral applications of the type intended for the Sapphire Plus STM 3W Diode Laser and describes how the Sapphire Plus STM Diode Laser is equivalent to these devices. Included in the Section "Clinical Reviews Related to the Sapphire Plus 3W Diode Laser" are references to meta-reviews, clinical studies, *in vitro* studies, and animal studies. The studies point to the 808 nm diode laser's affinity for hemoglobin and melanin and describe how this is particularly effective in soft tissue treatments and point to the

device's ability to achieve clinical objectives that are overall less painful and exhibit quicker recovery times than traditional surgical means. The studies support the contention that diode lasers that emit in this approximate wavelength are similarly effective and safe.

Conclusion

The subject device shares the same principle of operation as the three predicate devices. All are diode lasers that emit radiant energy at approximately 808 nm with outputs that range from 0.1 to 5.0W. All deliver collimated laser energy to subject target tissue via 400 μm silica optical fibers controlled by trained, experienced clinicians. All offer visible aiming beams that are adjustable and that may be turned off. All share the same indications for use in dental intraoral soft tissue general, oral maxilla-facial and cosmetic surgery. All have been found to satisfy international safety standards relating to electrical medical devices in general and medical lasers in particular. All share the similar safety labeling, device interlocks, and associated safety features. Both the subject and a predicate device's output were measured and compared to their settings to determine the accuracy of the devices' controls. Both met international standards pertaining to accuracy of output of the working beam, but the difference between the subject device's output and its setting was much less than the predicate's, demonstrating not only conformance to the standard, but also superior control over laser emissions.

The subject and the predicate devices share similar features and characteristics, from working beam lasing characteristics to control interfaces and status indicators. Laser energy for all devices is transferred to patient tissues via 400 μm silica optical fibers.

The Sapphire Plus STM Diode Laser shares intended uses, principle of operation, technical attributes, functional capabilities, and performance characteristics with the listed predicate devices. Both the subject and predicate devices have been shown to comply with applicable Federal and international safety and performance standards. The Sapphire Plus STM Laser performs it's surgical function using the same technological means as similar dental soft-tissue lasers whose safety and effectiveness has been reported in the literature. The Sapphire Plus STM Diode Laser is substantially equivalent to the listed predicate laser surgical devices and does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Den-Mat Holdings, LLC
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Ms. Paula Wilkerson
2307 East Aurora Road, Unit B7
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FEB 10 2011

Re: K110079
Trade/Device Name: Sapphire Plus STM 3W Diode Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: February 03, 2011
Received: February 07, 2011

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

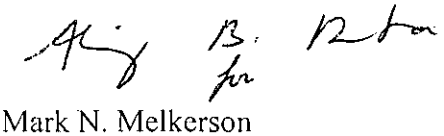
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110079

Device Name: Sapphire Plus STM 3W Diode Laser

Indications for Use:

The Sapphire Plus STM 3W Diode Laser is intended for use in dental intraoral soft tissue general, oral maxilla-facial and cosmetic surgery. It is intended for ablating, incising, excising, vaporizing and coagulation of soft tissues using a fibre optic delivery system. Indications include excision and incision biopsies; hemostatic assistance; treatment of apthous ulcers; frenectomy; frenotomy; gingival incision and excision; gingivectomy; gingivoplasty; incising and draining abscesses; operculectomy; oral papillectomy; removal of fibromas; soft tissue crown lengthening; sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket); tissue retraction for impression; and vestibuloplasty.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nilka Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110079